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May 21, 1999

Dockets Management Branch HFA-305
FDA
5630 Fishers Lane Room 1061
Rockville, MD 20852

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RE: Proposed change to 21 CFR 1010 and 1040

We routinely assist clients with FDA CDRH and IEC compliance and have the following comments to offer with regard to the proposed 21 CFR 1010 and 1040 regulations.

First in our view the most serious challenge facing the FDA in the matter of laser safety is current non-compliance. The most blatant noncompliance we have seen to date involves free space communication links employing 785nm laser diodes and specifically labeled as have "no regulatory compliance required" and advertised as shoulder mounted transmitters clearly at eye level. Unless the FDA proves a mechanism for enforcement the proposed changes are of little value.

Second to improve compliance among knowledgeable manufactures we recommend the number system of the proposed changes be modified to follow that of IEC 60825-1, wherein the cumulative number is shown for each section. Both the present and proposed regulations are numbered in such a way that it is very difficult to keep track of which section the reader is in. This will become clear as we refer to the following technical issues. Under the IEC numbering system a cumulative, nested numbering system is followed; such as 13.4.2. While retaining the current FDA sequence the equivalent numbering might be 13.i.a. At present the reader is only given a reference such as "a." without reference the current section and subsection. Likewise the three column format makes is significantly more difficult to follow the logical flow of the regulations as compared to the full page format of the IEC regulations.

To further improve compliance the FDA should follow the lead of the IEC is providing and appendix of class determination examples. Making it easier to understand how to apply these regulations will greatly increase compliance.

We have the following specific comments:

1. Under the current regulations importers are required to file an initial report even if the lasers are imported for resale as components. Is this also true under the proposed changes and if so under which section is this mentioned.

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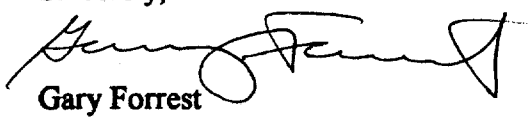
2. On page 14195 (Section 3.i.A.) the requirement is stated to measure beams in a 50mm aperture at a distance of 2 meters for sources outside the 400-1400 nm region.. The 2 meter distance seems impractical. What is the reason the variable distance/aperture method is not allowed for other sources ?

3. Table 7 refers to LEDs which are not included in the proposed changes.

3. Fiber optic systems, in particular those in which fibers can be removed by users (such as desktop Ethernet links) should be considered as they are under 60825-2. Current 850nm sources easily exceed Class 1 limits as will emerging 1300 and 1550 nm based systems. Given the very long lead time for proposed changes the issue of user fiber disconnects should be explicitly addressed in the same manner as the current regulations cover non-interlocked housings at present.

Sincerely,



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